Operational Support Tool 300-00-06B

LANL Unreviewed Safety Question Screening and Determination Procedure

Los Alamos National Laboratory

Developed by

Facility and Waste Operations Division
Office of Authorization Basis

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HISTORY OF REVISIONS

Revision	Date	Summary
0	03/19/01	Original Issue
1	04/04/01	Updated to incorporate DOE comments and minor editorial comments.
2	12/03/01	Revised requirement for PISA reporting, changed training requirements for Applicability Assessments, provided additional guidance for control of hazards during modification implementation process, replaced worksheets with revised ones in USQ standard, and incorporated minor editorial changes.

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1.0 PURPOSE

This procedure specifies the process for conducting Unreviewed Safety Question (USQ) Screens and/or Determinations for changes at (*insert facility name)*. When needed, it also provides a process for conducting a USQ Process Applicability Assessment (*If not needed, delete previous sentence)*. The USQ process allows the facility to make changes to support day-to-day operations. It also provides a mechanism for keeping the facility safety basis current by reviewing potential USQs, reporting USQs to DOE, and obtaining approval from DOE prior to taking any action that involves an USQ.

This procedure implements the requirements of LIR 300-00-06, LANL USQ Screening and Determination Standard (OST 300-00-06C), 10 CFR 830.203, the Implementation Guide to 10 CFR 830.203, and DOE Order 5480.21.

2.0 SCOPE

The USQ processes specified in this procedure are required for:

- all temporary or permanent physical changes at the facility,
- all temporary or permanent changes to procedures at the facility,
- all activities, operations, tests, or experiments that are new to the facility, and
- discoveries of potential inadequacies in the existing documented safety analysis.

This procedure not only applies to changes within the boundary of the facility, but also to changes outside the boundary, when those changes have the potential to affect the safety of the operations within the boundaries.

3.0 DEFINITIONS AND ACRONYMS

The acronyms and definitions of terms that are used in a special way in this procedure are provided in the LANL USQ Screening and Determination Standard, OST300-00-06C.

4.0 PRECAUTIONS AND LIMITATIONS

4.1 Determination of Facility Safety

The title of the process “Unreviewed Safety Questions” may suggest that the process determines the safety of changes. However, the USQ process is intended to determine the final approval authority for a change. It is not intended to replace or to serve instead of a safety analysis of the change. The safety implications of a change should be reviewed, analyzed, understood, addressed, determined to be acceptable, and documented separately from the USQ process. The change should already be known to be safe before it enters the USQ process.

The USQ process determines if final approval by the LANL is sufficient or if DOE review and approval are required. If the facility wants to implement changes, DOE must review and approve those changes that involve a USQ (that is, the USQD is positive) to verify that the safety controls are adequate to provide an acceptable level of safety to the public, the

environment, and workers. The existence of a positive USQD does not mean that the change is unsafe, but only that DOE must take the final approval action.

4.2 Control of Hazards During Installation Work Activity

Appropriate safety management programs (such as work planning and control that includes job hazard analysis or a similar process) should address hazards that may be involved during the installation of a modification. For worker protection, DOE relies on the LANL's commitment to various safety management programs to address the hazards involved in the actual installation of a modification, not the USQ process. These programs include radiation protection, hazardous material protection, work planning and control, OSHA, ALARA, and lockout/tagout. One basic tenet of the USQ process is to assess the potential change in probability and consequence risk factors that might be involved when facility operations are resumed after the modification is implemented.

However, sometimes a modification might be only partially implemented because it is interrupted by unforeseen circumstances. In such cases, the USQ documentation would need to be revisited to ensure that it adequately addresses operation with the partially implemented configuration.

During the installation period for construction, modification and routine maintenance activities at nuclear facilities, authorization basis/safety basis (AB/SB) requirements, including controls, may be violated in the absence of proper planning. The TSR/OSR/ITSR Limiting Conditions for Operation are expected to be the primary requirements that could be affected by actions taken or controls not implemented during the construction or maintenance period. TSR design requirements and administrative controls could also be affected. Work packages should include steps to address this issue. When temporary/interim equipment configurations are implemented that are not covered by the existing AB/SB, controls and/or compensatory measures should be included in the work package and reviewed in the USQ process. Removal of controls should be addressed in the planning process and the work package.

4.3 Graded Approach

The only application of the graded approach to the USQ process is indirect. The graded approach may give a rough indication of how much justification or basis information should be provided when explaining the answers to each of the seven USQD criteria. More elaborate and thorough basis information would be expected for changes to safety SSCs than for non-safety SSCs. In any case, the justification for the answers to the USQD criteria needs to be defensible.

4.4 Constraints

The USQ process is an inappropriate vehicle for establishing new constraints on the change. The change should be evaluated the way it is presented, not in some way that would enhance or improve the change from a USQ perspective. The USQ process must not establish or imply any constraints on the change.

5.0 QUALIFICATIONS AND TRAINING

Facility personnel responsible for preparing, reviewing, or approving USQ documents (screens or determinations) must receive initial training on the application of the Nuclear Safety Management rule and facility specific procedures. In addition, personnel must have the required educational background, work experience, knowledge of the facility, understanding of DOE requirements related to the generic safety basis (including the USQ process) and familiarity with the facility specific safety basis prior to participating in the USQ process.

The Safety Basis Manager with the support of the Training Coordinator will develop and implement a training and qualification program for facility personnel, who implement the USQ process. The Training Coordinator will develop and maintain a list of all personnel currently qualified to perform, review, and/or approve USQ Screens and Determinations. This list must be updated as required to ensure that the list is current and complete. Copies of the list of qualified personnel will be provided to the Facility Manager and Safety Basis Manager.

At a minimum, facility personnel preparing, reviewing, or approving USQ documents must have:

- A BS in engineering or one of the physical sciences or equivalent approved by facility management,
- Two years of experience at a nuclear facility, at least one year of which is at the facility where the USQs will be processed, or an approved equivalent level of experience,
- Satisfactory completion of the LANL Site-Specific Initial USQ training course, and
- Demonstrated knowledge of the facility Safety Basis. *(Insert facility specific training and qualification requirements)*

Personnel preparing USQ process applicability assessments must be appropriately qualified in the change control process. Additionally, facility personnel preparing USQ applicability assessments must have:

- At least one year experience at the facility where the USQs will be processed, or an approved equivalent level of experience,
- Satisfactory completion of the LANL Site-Specific Initial USQ training course, and
- Demonstrated knowledge of the facility Safety Basis.

Personnel preparing, reviewing, and approving USQ documents (screens or determinations) must maintain proficiency and be requalified nominally every 2 years. Proficiency is maintained by having performed, reviewed, or approved a minimum of four USQ Determinations over the two-year period. If proficiency is maintained, requalification may be achieved by the completion of the LANL site-specific re-qualification/refresher training class. If proficiency has NOT been maintained, re-qualification is achieved by the completion of the LANL site-specific initial USQ training class. If the individual does not complete requalification within 30 months, the qualification shall be expired.

Personnel who perform a technical subject matter expert (SME) review of USQ documents do not need to be qualified as a USQ preparer.

LANL management personnel who acknowledge USQ documents subsequent to the facility management approval of USQ documents shall complete as a minimum the USQ introductory training course on the USQ process.

6.0 RESPONSIBILITIES

Facility Manager	♦ Establishes and maintains the Authorization Agreement with DOE which identifies the current safety basis documents in accordance with LIR240-01-03. ♦ Ensures that USQ processes are integrated with facility activities, particularly change control. ♦ Oversees the USQ process at the facility. ♦ Approves the knowledge requirements for personnel preparing, reviewing and approving USQ screens and/or determinations at the facility. ♦ Approves all USQ determinations per requirements for approvers specified below. ♦ Approves requests for amendments to the facility safety basis. ♦ Ensures that potential inadequacies in the safety analysis are addressed in a timely manner in accordance with this procedure. ♦ In the absence of an assigned person, assumes the roles and responsibilities of the Safety Basis Manager.
Safety Basis Manager	♦ Implements the USQ process at the facility. ♦ Directs the training and qualification of USQ preparers, reviewers and approvers and USQ process applicability assessment preparers. ♦ Determines the facility specific knowledge requirements for personnel preparing, reviewing, and approving USQ screens and/or determinations. ♦ Maintains a list of the current safety basis documentation for the facility. ♦ Ensures that controlled copies of safety basis documentation are used to perform USQ screens and determinations. ♦ Assigns qualified personnel to prepare and review USQ screens and/or determinations. ♦ Approves USQ screens per requirements for approvers specified below. ♦ Reviews USQ determinations per requirements for reviewers specified below. ♦ Prepares requests for DOE approval of unreviewed safety questions. ♦ Implements a system for labeling and tracking USQ screens and determinations. ♦ Ensures that completed USQ documents are properly forwarded to records management for retention. ♦ Prepares the annual summary of USQ determinations for submission to the OAB. ♦ Advises management personnel on USQ issues. ♦ Reviews Tenant and Facility documents for USQ issues.

USQ process applicability assessment preparers	♦ Qualify and maintain proficiency on the USQ process applicability for the assigned facility (ies). ♦ Qualify and maintain proficiency on this aspect of change control. ♦ Maintain a thorough knowledge of the safety basis for the facilities to which they are assigned. ♦ Prepare assessments of the applicability of the USQ process in accordance with this standard.
USQ preparers, reviewers, and approvers	♦ Qualify and maintain proficiency on the USQ process for the assigned facility (ies). ♦ Maintain a thorough knowledge of the documented safety basis for the facilities to which they are assigned. ♦ Complete applicable portions of the USQ process as directed by this procedure for preparation, review and approval of USQ applicability assessments and USQ screens and/or determinations. ♦ Ensure that only the most current and controlled versions of safety basis documentation and procedures are used in this process.
Records Management and Document Control	♦ Maintains all USQ and safety basis documentation in a controlled and retrievable fashion.
The Facility Safety Basis Review Committee (Optional)	♦ If established, meets to discuss USQ screens and/or USQ determinations, as directed by the Facility Manager or designee.
Training Coordinator	♦ Assists the Safety Basis Manager in establishing and implementing the training and qualification program for USQ preparers, reviewers, and approvers and USQ process applicability assessment preparers, reviewers, and approvers. ♦ Maintains a list of qualified USQ preparers, reviewers, and approvers and USQ process applicability assessment preparers. ♦ Alerts the Safety Basis Manager and/or Facility Manager and qualified personnel when retraining is required.

7.0 PROCEDURE

7.1 GENERAL OVERVIEW

(The USQ process is a subpart of the broader change control process. To ascertain if it is necessary to enter the USQ process, change control procedures must as a minimum contain the steps outlined in section 7.2 to assess USQ process applicability. If the facility's USQ process IS NOT adequately integrated with the change control process, include the following italicized and underlined paragraphs, the italicized and underlined section in section 7.2, and attachment 1 in the procedure. If the facility's USQ process IS adequately integrated with the change control process, delete the following paragraphs, the italicized section in section 7.2, and attachment 1 from the procedure. Consult with the FWO-OAB if this is unclear or additional guidance is necessary.

Note: The applicability screen for proposed changes to programmatic or experimental operations presumes that a safety envelope (hazard analysis) has been established for each programmatic/experimental activity and that the sum of all such safety envelopes is bounded by the facility safety basis. As long as the programmatic/experimental envelope remains intact, the facility safety basis cannot be infringed upon. This step provides maximum programmatic/experimental flexibility to avoid curbing research creativity and still provides adequate safety protection. However, if the programmatic or experimental operations have not been the subject of a hazard analysis, the proposed change should be returned to the change control process to develop such an analysis.

The determination of the applicability of the USQ process to the situation is normally integrated into the facility's procedures and processes. However, if the USQ process is not well integrated with the facility's processes, the applicability of the USQ process to a particular situation is determined by performing a USQ process applicability assessment.

The general USQ process consists of two key steps:

- USQ Screening
- USQ Determination

The facility safety basis is the baseline point of reference for the USQ process. The Safety Basis Manager maintains a list of the specific documents that are currently designated to be part of the facility safety basis. Personnel involved in the USQ process should have ready access to copies of all safety basis documents. Those copies must be verified to ensure that only the versions that are currently part of the safety basis are used in the USQ process, such as through a controlled document process.

7.2 USQ PROCESS APPLICABILITY

Changes that do not enter the USQ process and do not require DOE approval

It is not necessary to enter the USQ process for every situation. In some of those situations, the change does NOT require DOE approval. These include:

a) Maintenance actions that involve the replacement of SSCs with an exact replacement (that is, same make, manufacturer, model number, etc.),

b) Maintenance actions that involve the replacement of SSCs with an Approved Equivalent Part (for which a facility engineer has determined and documented that the replacement part meets all the requirements relevant to the specific facility application),

c) Changes to programmatic operations (including experimental and research activities, hardware, software, and procedures) that remain within the safety envelope already approved for the operation or activity. This provision presumes that an appropriate safety envelope has been established, reviewed, and approved, and that the safety envelopes for all such programmatic activities are enveloped by the facility's documented safety analysis. This approach assures that as long as the safety envelope for a particular programmatic operation remains valid, the documented safety analysis for the facility cannot be in jeopardy. This approach provides the maximum programmatic flexibility while providing adequate safety protection. In order to be considered covered by the established safety envelope, the facility must demonstrate in a documented fashion that:

- *a hazard analysis (safety envelope) has been established for each programmatic operation, and*
- *the change to an existing programmatic operation will not adversely impact the hazard analysis (safety envelope) for that operation.*

These steps provide maximum programmatic flexibility to avoid curbing creativity and still provide adequate safety protection,

d) A non-conforming part is restored to become compliant with the requirements. In a typical QA program, there is a set of standard dispositions for non-conformances. These may include: a "reject" disposition in which the non-conforming part is replaced with a conforming part, a "Use-As-Is" disposition in which the non-conforming part is justified as not meeting all functional requirements but is nonetheless an acceptable part, a "repair" disposition in which the part is made to agree better with the requirements for the part (but it remains not fully compliant with the requirements), and a "rework" disposition in which the part is restored to the point that it becomes fully compliant with the requirements, (NOTE: Discovery of a nonconforming part in an operating system, requires that the facility evaluate the operability of the system and take appropriate steps to report the condition and place the facility in the required operating mode.)

e) Modifications to return to the original condition as corrective action to resolve discrepant as-found conditions (i.e. exact restoration), [If the disposition of the discrepant as-found condition is a "restoration modification", then this corrective action hardware modification will exit the USQ process. If not, the as-found condition must be considered further within the USQ process],

f) Purely editorial changes that do not affect the technical content.

When there is a question as to whether or not the USQ process is applicable to a proposed activity, the USQ process applicability assessment is the method for determining whether or not it is necessary to apply the USQ process.

Attachment 1 to this procedure provides the worksheet to be used for the USQ process applicability assessment. Except where specifically instructed otherwise, all the steps of the USQ process applicability assessment are to be completed. The questions included in the USQ process applicability assessment section are intended to provide a method for documenting those activities or changes that do not require entry into the USQ process.

Changes that do not enter the USQ process but do require DOE approval.

The USQ process is not applicable to situations that are beyond the scope of day-to-day operations, and hence LANL is required to submit those changes to DOE for approval. Such situations include:

a) Changes that introduce a technology that is new to the facility,
b) Changes that are major modifications, in that they go beyond those necessary for day-to-day operations,
c) Changes that management has predetermined to submit to DOE for safety review and approval, and
d) Changes to the TSRs.

If the change introduces a technology that is new to the facility (for example, a high energy x-ray machine at a facility that has not previously had similar equipment), the change is beyond the intended scope of the USQ process (as envisioned by DOE 5480.21) and hence requires approval by DOE prior to implementation.

The USQ process is not applicable to major modifications. Because they have a major impact on the existing safety basis of the facility, DOE must approve them. In most cases the safety document associated with such a change is a preliminary documented safety analysis. [10 CFR 830.206(b)]

The Nuclear Safety Management rule requires that changes to the TSRs be submitted to DOE for review and approval. A change to the TSRs could involve the need either to modify an existing TSR or to add a new TSR. If the entirety of the change is merely a change to the requirement of the TSRs, then that change should be submitted to DOE for review and approval without having to perform a USQ screen or USQD. However, most real-world changes involve something more, such as a procedure change, a physical change, or a new activity. In those situations, it is necessary to point out that the whole change must be submitted, not simply the word change for the TSR without the underlying change. The basis for not having to go through the USQ steps is that the entire change is already going to DOE. If the whole change were not already going to DOE, it would become necessary to complete the USQ steps.

The scenarios above require the facility to request an amendment to the facility safety basis. The preparation of such a request is discussed in Section 7.6 below.

7.3 USQ SCREENING

Changes that are not eliminated during the USQ process applicability assessment need to go through a formal USQ screening. (Delete preceding sentence if the USQ applicability

assessment is not part of the facility procedure.) USQ screening criteria are to be applied to those facility modifications or changes that enter the USQ process, but which may not need a detailed screen and/or determination. USQ screening is intended to be a simple Go/No-Go decision-making step, without evaluative consideration.

A USQ qualified person must perform the USQ screening.

The USQ screening worksheet in attachment 2 addresses the USQ screening steps in detail. Except where specifically instructed otherwise, all the steps of this form are to be completed.

Complete the Unreviewed Safety Question Screening and Determination Worksheet cover sheet. In Section 1, provide (or reference) a detailed description of the change that is being considered and provide the references that will be used to support the screen and/or determination.

The responses to the following questions in Section 2 of the worksheet will determine if a USQ determination is required. If the change does not screen out of the USQ process based on the answers to the first three questions (Section 2.1), it will be necessary to complete Section 2.2 and identify the possible impacts of the change. This information will be used to support the answers to the final three questions (Section 2.3) in the screening process.

1. Is this a purely editorial change that does not affect the technical content?

2. Is this change covered by a DOE approved Categorical Exclusion?

3. Is this change covered by a previous USQD?

4. Is this a temporary or permanent change in the facility as described in the documented safety analysis?

5. Is this a temporary or permanent change in the procedures described in the documented safety analysis?

6. Is this a test or experiment that is not described in the documented safety analysis?

It is important that the screening process does not inappropriately screen out conditions requiring a USQD. A basis for the answer to each of the questions must be provided. Guidance for answering the screening questions can be found in LANL Standard OST 300-00-06C.

Complete the USQ Screening Summary and the coversheet, as appropriate. If a USQ determination is not required, complete the review of the USQ Screen as specified in Section 7.5. If a USQ determination is required, continue with Section 7.4.

7.4 UNREVIEWED SAFETY QUESTION DETERMINATION

The USQD serves two primary functions:

- It determines the approval authority of the change.
- It documents the technical basis for the conclusion reached.

If one of the entry conditions is met during the screening process, a USQD must be completed.

A USQ qualified person must perform the USQ determination.

The USQ screening and determination worksheet in attachment 2 addresses the USQ determination steps in detail. To complete the USQ determination all seven questions on the form are to be completed.

If not completed previously, complete the Unreviewed Safety Question Screening and Determination Worksheet cover sheet. In Section 1, provide (or reference) a detailed description of the change that is being considered and provide the references that will be used to support the screen and/or determination. In Section 2.2 identify the items in the documented safety analysis that are potentially impacted by the change.

Complete the following seven questions in Section 3 of the worksheet to determine if an unreviewed safety question exists. If any of these questions is answered "Yes," the determination is said to be positive, the change is said to involve a USQ, and, if implementation is desired, DOE must approve the change prior to implementation. The USQ determination requires consideration of the documented safety analysis for the nuclear facility (or other DOE approved documentation that provides the safety basis for operations or other activities) and the specific details of the change. Guidance for answering the seven questions can be found in LANL Standard OST 300-00-06C.

Provide a defensible explanation for the answers to each of the USQ criteria. The explanation must capture the technical basis for each of the answers.

1. Could the Proposed Change[1] Increase the Probability of Occurrence of an Accident Previously Evaluated in the Documented Safety Analysis?

2. Could the Proposed Change Increase the Consequences of an Accident Previously Evaluated in the Documented Safety Analysis?

3. Could the Proposed Change Increase the Probability of Occurrence of a Malfunction of Equipment Important to Safety Previously Evaluated in the Documented Safety Analyses?

4. Could the Proposed Change Increase the Consequence of a Malfunction of Equipment Important to Safety Previously Evaluated in the Documented Safety Analysis?

5. Could the Proposed Change Create the Possibility of an Accident of a Different Type than any Previously Evaluated in the Facility's Documented Safety Analysis?

6. Could the Proposed Change Create the Possibility of a Malfunction of Equipment Important to Safety of a Different Type than any Previously Evaluated in the Documented Safety Analysis?

7. Could the Proposed Change Reduce the Margin of Safety?

Complete the USQ Determination Summary and the coversheet, as appropriate.

[1]For the purposes of this procedure, "change" will mean any change to procedures or equipment (including prior undocumented changes), any new tests or experiments, or any new information that has the potential to invalidate the safety basis.

7.5 USQ Reviews and Approval

USQ screens and determinations are prepared by one individual and then reviewed technically by a second person. The technical reviewer must be independent in the sense that he/she has not been involved in the preparation of the USQ screen and/or determination, but does not need to be organizationally independent.

When the preparer has completed the USQ screen and/or determination, he/she will forward the screen and/or determination to the technical reviewer. The technical reviewer will conduct an independent assessment of the USQ screen and/or determination. Review comments will be provided to the preparer and resolved prior to sign off of the reviewThe USQ determination will be provided to the SME for sponsoring organization review prior to final approval.

The sponsoring organization for a change might be a programmatic group or might be the facility management team. To ensure appropriate coordination between the sponsoring organization and the USQ processing organization, a subject mater expert in the sponsoring organization should review the USQ determination. This review should ensure the accuracy of the description and understanding of the change and the accuracy of the hazards and risk factors associated with the change. It should also verify that the risk control measures (preventive and mitigative measures) are appropriate and consistent with those that are already part of the change. This review also establishes agreement between the sponsoring organizations and the preparer on the change as it is described and evaluated in the USQ documents.

The USQ screen and/or determination will then be forwarded to the Safety Basis Manager and the Facility Manager (USQD) for review and approval.

After approval, the USQ screen and/or determination may be forwarded to other management personnel for review and acknowledgement if desired.

Once the USQ screen and/or determination has been completed and approved, the screen and/or determination will be forwarded to the appropriate reviewing officials for derivative classification and uncontrolled nuclear information (UCNI) determinations.

7.6 Requests for Amendments to the Facility Safety Basis

The following format will be used for submitting unreviewed safety questions or changes beyond the scope of day-to-day operations to the DOE. The Safety Basis Manager will prepare a memorandum from the Facility Manager addressed to the Senior Authorization Basis Manager of DOE/LAAO requesting approval of the proposed change or activity.

To the maximum extent practical and appropriate, the memorandum should address the following topics, as applicable:

1. An introductory summary of the purpose of the memorandum and its contents,
2. A description of the proposed change or activity that generated the need for action,
3. A summary of the applicable safety analyses, such as:
    - Failure modes and effects analysis,
    - Calculations of affected accident probabilities and/or consequences,
    - Engineering and/or technical considerations,
    - Alternative actions and associated safety implications and
    - The selected action and supporting reasoning,

4. A summary of the results of the USQ determination,
5. Programmatic, budgetary, and schedule considerations,
6. Conclusion of the safety analysis upon which DOE is requested to approve the proposed change or activity.
7. A clear presentation of the required controls.

The completed USQ documents should be enclosed with the memorandum. The safety analysis documentation and supporting analyses, calculations, etc. that are necessary to establish the safety of the proposed change or activity (and for DOE to evaluate the request) should also be enclosed.

The request memorandum should then be forwarded to the OAB for concurrence and transmittal to DOE.

7.7 USQ DOCUMENT TRACKING

The Safety Basis Manager will implement a system for tracking the status of the USQ documents (screens and determinations). The system must provide the capability to track the status of the screen and/or determination from initiation through approval and closeout. Potential items to include in the database are: the change number, the process applicability assessment number, the unreviewed safety question screen and/or determination number, document title, brief description of change, date approved, date implemented, date cancelled, date incorporated into documented safety analysis, screened out at applicability, screen, negative USQD, positive USQD.

8.0 POTENTIAL INADEQUACY OF THE DOCUMENTED SAFETY ANALYSIS

A PISA may arise from any of three generic types of entry conditions: 1) a discrepant as-found condition, 2) an operational event or incident, and 3) new information. New information includes: New information sent by a vendor, technology advances, or the discovery of errors and omissions in an analysis. Analytical errors include: Use of an improper model, inappropriate assumptions associated with that model, incorrect input values, incorrect calculations, or inappropriate interpretation of results.

Any time an individual has reason to believe that the facility's safety basis might be inadequate, the situation must be reported to management immediately. The Facility Manager is then allowed a "reasonable time" to confirm the existence of the potential for an inadequate documented safety analysis prior to entering the PISA part of the USQ process. This "reasonable period" is typically a few hours up to a day or so. It is not days, weeks, or months.

In the event the facility discovers a condition that is contrary to the documented safety analysis, the condition must be evaluated to determine if a PISA exists. This involves evaluating a hardware discrepancy as if it were a proposed change ("backward-looking USQ") or evaluating an analytical error with the error as corrected. If a PISA is identified, follow the steps outlined below.

After the Facility Manager has confirmed the potential for an inadequate documented safety analysis, the following actions are required:

1. Take action, as may be necessary and appropriate, to ensure the safety of personnel and to place or maintain the facility in a safe condition, at least until an evaluation of the safety of the situation is completed.

2. Notify the DOE (normally the Facility Representative) of the situation. Declare as Off-Normal only if "Significant Compensatory Measures" are required per Laboratory Occurrence Reporting Requirements/ Guidance, OST 402-130-01.
3. Perform a USQD on the situation. The time period for the performance of a USQ determination related to a PISA should be on the order of days, not weeks or months. [10 CFR 830; final rule; 01/10/01; response to comment "Q"]
4. Promptly notify DOE of the results of the USQD. Although not required by DOE, the LANL requires submittal of the USQD to the DOE through the OAB.
    - If the USQD is negative, an actual inadequacy of the documented safety analysis does not exist.
    - If the outcome of the USQD is positive, an actual inadequacy of the documented safety analysis exists. Report this situation to the DOE as an Unusual Occurrence per Laboratory Occurrence Reporting Requirements/ Guidance, OST 402-130-01. This report must explicitly identify the occurrence as a PISA.
5. Submit the evaluation of the safety of the situation to DOE through the OAB in accordance with section 7.6.
6. Operational restrictions initiated to meet item 1 above must be maintained until the evaluation of the safety of the situation has been submitted to DOE, and:
    - the USQD is negative, or
    - the USQD is positive and DOE has approved removal of the operational restriction(s).

9.0 DOCUMENTATION AND REPORTING

9.1 DOCUMENT RETENTION

The USQ documents are maintained for the full operational life of the facility.

Completed USQ screens and determinations will be forwarded to records management for retention.

9.2 ANNUAL USQ SUMMARY

Annually in January, the Safety Basis Manager will prepare a summary of all the USQ determinations that have been completed since the last submission. This summary will contain the following information for each USQD: The number and title of the USQD and a brief summary of the matter (a few sentences).

The summary will be forwarded to the OAB by January 31st for subsequent submission to DOE.

ATTACHMENT 1

USQ PROCESS APPLICABILITY ASSESSMENT WORKSHEET

Los Alamos NATIONAL LABORATORY	**USQ PROCESS APPLICABILITY ASSESSMENT WORKSHEET**	
Change number:		Date:
Facility-Specific Unreviewed Safety Question Process Applicability Assessment Number:		
Facility Identification:		
Change description:		
Based on the evaluation presented in this worksheet: ☐ The USQ process IS APPLICABLE, and USQ Screening will be performed (NOTE: A hazard/safety analysis must be provided as appropriate) ☐ The USQ process is NOT APPLICABLE to this situation, and ☐DOE review and approval is NOT REQUIRED, or ☐DOE review and approval IS REQUIRED, and a Request for Amendment to the Facility Safety Basis should be prepared.		

SIGNATURES

Assessment Preparer's Signature Typed or printed name of assessor	Date
Acknowledging Manager's Signature Typed or printed name of acknowledging manager	Date

Retain original copy per facility records management procedures.

This document was reviewed to ensure proper classification: ☐ Unclassified ☐ UCNI ☐ Classified	
ADC Signature Typed or printed name of ADC	Date
UCNI Reviewing Official Signature Typed or printed name of UCNI reviewing official	Date

APPLICABILITY ASSESSMENT

In assessing the applicability of the USQ process to various situations, it is realized that: (1) some changes do NOT require USQ processing and do NOT require DOE approval, (2) some changes do NOT require USQ processing but DO REQUIRE DOE approval, and (3) if not covered by the first two cases, become mandatory inputs to the USQ process.
NOTE: The number in brackets following the questions below is a reference to the corresponding section of the standard.

1. If the answer to any of the questions in Section 1 is "Yes," the change does NOT require entering the USQ process and does NOT require DOE approval

   a. Is this a maintenance action that involves the replacement of equipment with an exact replacement? [8.2.1.a] ☐ Yes ☐ No

   b. Is this a maintenance action that involves the replacement of equipment with an approved equivalent part? [8.2.1.b] ☐ Yes ☐ No

   c. Is this a change to programmatic operations and/or programmatic hardware that remains within the safety envelope of the approved hazard analysis for those operations? [8.2.1.c and 8.2.3] ☐ Yes ☐ No

   d. Is the non-conforming part restored to become compliant with the requirements (i.e. the non-conformance report is dispositioned "reject" or "rework")? [8.2.1.d] ☐ Yes ☐ No

   e. Is this change part of a corrective action for a discrepant as-found condition, and is the action a restoration modification (return to the original condition)? [8.2.1.e] ☐ Yes ☐ No

   f. Is it an editorial change to a procedure or document? [8.2.1.f] ☐ Yes ☐ No

2. If the answer to any of the questions in Section 2 is "Yes," the change does not require entering the USQ process; however, does require DOE review and approval. Therefore, if there is a "Yes" answer, a Request for Amendment of the Safety Analysis should be prepared (See section 8.6 of the USQ Standard).

   a. Is this a change that introduces a new technology to the facility? [8.2.2.a] ☐ Yes ☐ No

   b. Is this a change that is a major modification, in that it goes beyond that necessary for day-to-day operations? [8.2.2.b] ☐ Yes ☐ No

   c. Has management decided to submit the proposed change to DOE for review and approval? [8.2.2.c] ☐ Yes ☐ No

   d. Is this a change to the TSRs? [8.2.2.d] ☐ Yes ☐ No

☐ The USQ process IS APPLICABLE, and USQ Screening will be performed (NOTE: A hazard/safety analysis must be provided as appropriate)

☐ The USQ process is NOT APPLICABLE to this situation, and
- ☐ DOE review and approval is NOT REQUIRED, or
- ☐ DOE review and approval IS REQUIRED, and a Request for Amendment to the Facility Safety Basis should be prepared.

Complete the cover sheet summary.

ATTACHMENT 2

USQ SCREENING AND DETERMINATION WORKSHEET

Los Alamos NATIONAL LABORATORY	**UNREVIEWED SAFETY QUESTION SCREENING AND DETERMINATION WORKSHEET**
Change number:	Date:
Facility-Specific Unreviewed Safety Question Number:	
Facility Identification:	
Change description:	
Based on the evaluation presented in this report, the change: ☐ entered this process as a PISA ☐ has been screened out of the USQ process and does not constitute an Unreviewed Safety Question ☐ does not constitute an Unreviewed Safety Question based on a full USQD ☐ constitutes an Unreviewed Safety Question and **DOE approval is required** prior to implementation	

SIGNATURES

Preparer's Signature Typed or printed name of preparer	Date
Reviewer's Signature Typed or printed name of reviewer	Date
Sponsoring Organization Reviewer's Signature Typed or printed name of sponsoring organization reviewer	Date
Approver's Signature Typed or printed name of approver	Date
Acknowledging Manager's Signature Typed or printed name of acknowledging manager	Date

Retain original copy per facility records management procedures.

This document was reviewed to ensure proper classification: ☐ Unclassified ☐ UCNI ☐ Classified	
ADC Signature Typed or printed name of ADC	Date
UCNI Reviewing Official Signature Typed or printed name of UCNI reviewing official	Date

SECTION 1: INTRODUCTION

1.1 DETAILED DESCRIPTION OF CHANGE

Provide a concise but detailed description of the proposed change. Include references to specific FSAR/BIO process descriptions where applicable. This section should clearly explain the relationship of the change to the process. (e.g. is this a component no longer required for the existing process [i.e. a legacy issue], or is this change in preparation for a new process to be approved in a separate USQD), discuss phases of the project including construction, start-up, normal operation, and provide one-line drawings, logic diagrams, and other reference drawings, as appropriate. Cite MAR and significant chemicals (amount, form, confinement, controls), energy sources and other significant hazards.

NOTE: The number in brackets following the questions below is a reference to the corresponding section of the standard.

1.2 REFERENCES

a) List documents and analyses that constitute the current safety basis for the facility/process

b) List other references used to support the evaluation

c) List hazard analyses/safety analyses that support the conclusions reached in this worksheet

NOTE: If applicable and if a hazard or safety analysis has not been provided, the change should be returned to change control to develop such an analysis.

SECTION 2: USQ SCREENING

2.1 Screening – Part I

If a USQD must be performed because USQ screening is not applicable (PISA), complete Section 2.2 and continue to Section 3 to complete the USQD.

a. Is this a purely editorial change that does not affect the technical content? [8.3.1.a] ☐ Yes ☐ No

b. Is the change covered by a DOE approved categorical exclusion? [8.3.1.b] ☐ Yes ☐ No

c. Is this change completely enveloped by a previous USQD? [8.3.1.c] ☐ Yes ☐ No

If any answer to any question in Section 2.1 above is “Yes”, the change does not require a USQ Determination. Continue to the Summary of Section 2. Otherwise continue below.

2.2 Impacts [8.3.2]

a. Identify all Safety Basis documents, procedures, tests and experiments that may be impacted by this change (e.g. FSAR, TSRs, Procedures, etc.) [8.3.2.a]:

b. Identify all accidents evaluated in the facility Safety Basis that may be impacted by this change [8.3.2.b]:

c. Identify all safety SSCs described in the current Documented Safety Analysis that may be impacted by this change [8.3.2.c]:

d. Identify all equipment important to safety other than safety SSCs that may be impacted by this change [8.3.2.d]:

e. Identify credible dominant failure modes, process parameters, and malfunctions associated with this change [8.3.2.e]:

2.3 Screening – Part II

a. Is this a temporary or permanent change in the facility as described in the existing documented safety analysis? [8.3.3.a] ☐ Yes ☐ No

b. Is this a temporary or permanent change in the procedures as described in the existing documented safety analysis? [8.3.3.b] ☐ Yes ☐ No

c. Is this a test or experiment not described in the existing documented safety analysis? [8.3.3.c] ☐ Yes ☐ No

Basis for your answers (reference documents reviewed):

If the answer to any question in Section 2.3 above is "Yes", a USQ Determination must be performed. Continue to Section 3 after completing the Summary section below.

USQ Screening Summary:

Based on answers to the screening questions above:

☐ this change does not require a USQ Determination. Complete the cover sheet summary.

☐ this change requires a USQ Determination. Complete Section 3.